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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,819	04/19/2005	Masayuki Kawakami	LEDER-0010	5431
23599 7590 02/26/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER JONES, DAMERON LEVEST	
			ART UNIT 1618	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		02/26/2007	PAPER	

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/506,819	<b>Applicant(s)</b> KAWAKAMI ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 7/26/05 & 4/19/05.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>7/26/05 &amp; 4/19/05</u> . | 6) <input type="checkbox"/> Other: _____  |

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## ACKNOWLEDGMENTS

1. The Examiner acknowledges receipt of the amendment filed 4/19/05 wherein claims 3-11 were amended.

**Note:** Claims 1-11 are pending.

## APPLICANT'S INVENTION

2. Applicant's invention is directed to compounds as set forth in independent claim 1 useful as imaging agents.

## DOUBLE PATENTING REJECTIONS

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-7 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,939,975.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to cyanine dyes. The claims differ in that those of the instant invention specifically state that the compounds are fluorescent contrast agents and the variables m1, m2, and m3 are 0 or 1 while the patented invention discloses that m1, m2, and m3 are 1. Thus, a skilled practitioner in the art would recognize that the patented invention is encompassed by the instant invention when m1, m2, and m3 are 1. In addition, a skilled practitioner in the art would recognize that compounds are inseparable from their properties, thus, since both the instant and patented invention disclose overlapping species, those species would be expected to behave the same. Hence, if Applicant's compounds fluoresce the patented compounds would also fluoresce.

## 112 SECOND PARAGRAPH REJECTIONS

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-11: The claims as written are ambiguous because the wording of independent claim 1 is confusing. In particular, it is noted that line 13 contains a period after the second occurrence of the word 'of'. Thus, it is unclear whether Applicant intended to add additional text or delete the text appearing after the period. In addition, Applicant is respectfully requested to review the claim and pay special attention to the provisos appearing in the claim. In particular, Applicant should review the provisos for clarity. Since claims 2-11 depend upon independent claim 1 which is confusing, those claims are confusing as well.

Claim 1, lines 9-10: The claim as written is confusing because it states that R3, R4, R5, R6, R9, R10, R11, and R12 may bind to each other to form a ring. Specifically, the variables all do not bind to one another to form a ring. It is groups of twos that bind to form a ring. Thus, Applicant is respectfully requested to clarify the claims in order that one may readily ascertain what is being claimed.

Claim 1, line 18: Should 'substituent' be 'substitutents' because more than one substituent is necessary in order to form a ring?

Claims 9 and 10: The claims are not further limiting. Did Applicant intend to write 'A method of tumor imaging....' for claim 8 and 'A method of angiography...' for claim 9?

### 103 REJECTIONS

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-4 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoki et al (EP 1,152,008, document was listed on IDS).

**Shinoki et al** disclose fluorescent nucleotides containing cyanine for detecting nucleic acid. In particular, Shinoki et al disclose Compounds 2 and 4 that meet the requirement of Applicant's invention when R4 and R10 = halogen; R7, R8, R1, and R2 = alkyl; X1 = substituted alkyl with 1 carboxyl group; X2 = substituted alkyl; m1 and m2 = 1; and m3 = 0 (Compound 2); and R4 and R10 = halogen; R1, R2, R7, and R8 = alkyl; X1 = substituted alkyl with 1 carboxyl group; X2 = substituted alkyl; m2 and m3 = 0; and m1 = 1 (Compound 4). Thus, both Applicant and Shinoki et al disclose overlapping compounds.

It would be obvious to one of ordinary skill in the art at the time the invention is made that since both Applicant and Shinoki et al disclose overlapping species and since compounds are inseparable from their properties that if Applicant's products fluoresce in

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the near infrared region, then Shinoki et al compounds would also fluoresce in the near infrared region.

9. Claims 1, 2, 5, 6, and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Achilefu et al (US Patent No. 6,395,257).

**Achilefu et al** disclose dyes useful for imaging, diagnosis, and therapy (see entire document, especially, abstract). In particular, the dyes may have Formulae 1 and 2 as set forth in column 2 (lines 35-67) and column 3 (lines 5-25). In Formula 1, for example, Achilefu et al disclose overlapping species wherein W1 and X1 are CR10R11; Q1 is a single bond; Y1 and Z1 are independently (CH2)c-CO2H, CH2-(CH2-O-CH2)d-CH2-CO2H; CH2-N(R14)-(CH2)h-CO2H; and (CH2)f-N(R15)-CH2-(CH2-O-CH2)j-CH2-CO2H; R2 and R9 may be C1-C10 aryl; R1 is hydrogen; and R10 and R11 are hydrogen. Thus, for Applicant's variables, X1 and X2 are carboxylalkyl groups; and R3-R6 are aryl groups. Formula 2 would have similar variable definitions, with the exception that two of the R groups on the six-membered ring connected to the five-membered nitrogen containing ring combine to form an aryl group. In column 15, a species is disclosed wherein when A is CH2 or CH2OCH2; R1 and R2 are hydrogen or R1 and R1 together form a fused phenyl; and R' and R are COOH is encompassed by the instant invention (for the instant invention m1, m2, and m3 = 1; X1 and X2 are both an alkyl substituted with a carboxyl group, R, R2, R7 and R8 = alkyl (i.e., methyl group); n = 1, and M+ = H). In addition in columns 5-6, bridging paragraph, it is disclosed that the dyes may be used for various biomedical applications include imaging of organs,

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coronary angiography, fluorescence endoscopy, as well as for the detection, imaging, and therapy of tumors. Thus, both Applicant and Achilefu et al disclose overlapping species that are useful for imaging tumors and angiography.

10. Claims 1, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinoki et al (EP 1,152,008) in view of Achilefu et al (US Patent No. 6,395,257)

**Shinoki et al** (see discussion above) fail to disclose that their compound may be used for tumor and angiography imaging. However, a skilled practitioner in the art would recognize that since both Shinoki et al and **Achilefu et al** (see discussion above) disclose structurally similar compounds, then one would expect that the compounds of Shinoki et al would also be useful for imaging tumors and angiography as disclosed in Achilefu.

Since both Shinoki et al and Achilefu et al disclose structurally similar cyanine dyes, the references would be considered to be within the same field of endeavor. Thus, the reference teachings are combinable.

## CLAIM OBJECTION

11. Claim 8 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Note:** Claim 8 is distinguished over the prior art of record because the prior art neither anticipates nor renders obvious the limitations in claim 8 in combination with the limitations of its intervening claims.



## **COMMENTS/NOTES**

12. It is duly noted that Applicant has filed numerous applications with overlapping subject matter. Thus, while the Examiner has made every effort to look at all the pending applications for double patenting rejections, some applications may have been missed in the process. Hence, Applicant is respectfully requested to subject application numbers containing overlapping subject matter.

13. For clarity of independent claim 1, the following are suggested: (1) line 5, replace the first occurrence of 'and' with 'or'; (2) line 6, replace 'may bind' with 'binds'; (3) line 9, replace 'and' with 'or'; (4) line 10, replace 'may bind' with 'binds'; (5) line 18, replace 'may bind' with 'binds'; (6)


14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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D. L. Jones  
Primary Examiner  
Art Unit 1618

February 16, 2007